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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,981	02/08/2005	Robert Charles Rees	000487.00034	1140

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EXAMINER	
BRISTOL, LYNN ANNE	
ART UNIT	**PAPER NUMBER**
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,981	REES ET AL.	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-18 are all the claims subject to lack of unity restriction.

2. It is noted that the peptide sequence in Claim 13 is does not meet the requirements under 37 C.F.R. §§ 1.821-1.825 for the reason(s) in that Applicants have not provided a sequence identifier. Applicants are required to identify the sequence by SEQ ID NO: in their response to this action.

Lack of Unity: Restriction

3. Restriction is required under 35 U.S.C. 121 and 372.

The claims of the present application relate to nucleic acids comprising a sequence of SEQ ID NO:1 (TACC1 splice variant); SEQ ID NO:2 (AD034; ROI1/ZK632.3/MJ0444 family of protein kinases); and SEQ ID NO:3 (AD034 splice variant), proteins or peptides encoded by the same, kits comprising the nucleic acids or protein/peptides and methods of using the nucleic acids or proteins/peptides. Generic claim 1 is drawn to a method of detecting or monitoring cancer comprising detecting the levels of nucleic acids for SEQ ID NOS: 1, 2 or 3 or proteins/peptides encoded by nucleic acids for SEQ ID NOS: 1, 2 or 3.

In assessing whether the requirements of unity of invention of an application are met, identification of the technical features that each solution to a technical problem contributes over the prior art (special technical features) must be made. If then a technical relationship between the solutions, involving one or more of the same

technical features, can be recognized, the requirements of unity of invention are said to be met.

Nucleic acids comprising SEQ ID NOS: 1, 2 and 3 were already known before the priority date of the present application. The use of nucleic acids in identifying their expression in relation to detecting and monitoring cancer was also a technical feature disclosed in the prior art.

For example, Line et al. (Br. J. Cancer 86:1824-1830 (June 2002)) disclose using the SEREX method as taught by the instant application to identify gastric cancer genes for detection and monitoring cancer progression. Line teaches the gene, Ga55 (TACC1) (Table I) identified by the SEREX method and highly expressed in gastric cancer. Ga55 represents a TACCI isoform generated by inclusion of alternative 36 bp exon, strongly expressed in gastric cancer tissues and weakly detectable in normal kidney and colon tissues but not in normal tissues (p. 1872, Col. 1, ¶ 3; Figure 1). Absent a showing to the contrary, the sequence for the TACC1 splice variant (SEQ ID NO: 1) would have been inherent to the Ga55 gene of Line.

Smith (WO/200264762; published 8/22/02; priority to 2/12/01) teaches a nucleic acid and peptides encoded thereby used in the diagnosis and prognosis of cancer, especially gastric cancer. Based on the attached sequence search output for sequence alignment of SEQ ID NO:2 with the sequence of Smith, the Smith gene would be considered the same or as corresponding to AD034 gene of the instant claims. Smith also teaches splice variants for the nucleic acid which would encompass the nucleic acid of SEQ ID NO:3, a splice variant of AD034.

Because the technical features of the claims are not a contribution over the prior art, the requirements for unity of invention with respect to the species of nucleic acids of SEQ ID NOS: 1, 2 and 3 has not been met.

4. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. The resulting separate inventions, as presently identified, have been grouped according to the order in which they have been claimed.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5 and 8, drawn to a method of detecting or monitoring a cancer comprising detecting levels for the nucleic acid sequence comprising SEQ ID NOS: 1, 2 or 3.

Group II, claim(s) 1 and 6-8, drawn to a method of detecting or monitoring a cancer comprising detecting levels for a protein/peptide encoded by the nucleic acid sequence comprising SEQ ID NOS: 1, 2 or 3 and using an antibody against the protein/peptide.

Group III, claim(s) 9 and 13-15, drawn to a kit comprising a nucleic acid molecule of SEQ ID NO: 1, 2 or 3 or a nucleic acid probe hybridizing to a nucleic acid of SEQ ID NO: 1, 2 or 3; a nucleic acid molecule encoding the peptide sequence of Claim 13; a vector comprising the nucleic acid of Claim 13; a nucleic acid comprising at least 15 nucleotides and hybridizing with a nucleic acid of Claim 13.

Group IV, claim(s) 9, drawn to a kit comprising an antibody recognizing a protein/peptide encoded by a nucleic acid of SEQ ID NO: 1, 2 or 3.

Group V, claim(s) 10 and 11, drawn to a method of prophylaxis or treatment of cancer comprising administering a nucleic acid comprising a sequence of SEQ ID NO: 1, 2 or 3 or a nucleic acid molecule hybridisable to a nucleic acid of SEQ ID NO: 1, 2 or 3.

Group VI, claim(s) 10 and 11, drawn to a method of prophylaxis or treatment of cancer comprising administering a protein/peptide encoded by a nucleic acid comprising a sequence of SEQ ID NO: 1, 2 or 3.

Group VII, claim(s) 10 and 11, drawn to a method of prophylaxis or treatment of cancer comprising administering an antibody recognizing a protein/peptide encoded by a nucleic acid comprising a sequence of SEQ ID NO: 1, 2 or 3.

Group VIII, claim(s) 12, drawn to a vaccine comprising a nucleic acid of SEQ ID NO: 1, 2 or 3, and a pharmaceutically acceptable carrier.

Group IX, claim(s) 12, drawn to a vaccine comprising a protein/peptide encoded by nucleic acid of SEQ ID NO: 1, 2 or 3, and a pharmaceutically acceptable carrier.

Group X, Group XI, claim(s), 16-18, drawn to a polypeptide or peptide obtainable from the nucleic acid of Claim 13; a polypeptide or peptide obtainable from the vector encoding the nucleic acid of Claim 13; a polypeptide or peptide obtainable from a nucleic acid hybridizing to the nucleic acid of Claim 13.

5. As no technical features can be distinguished which, in light of the prior art, could be regarded as special technical features on which a unifying concept could be based, there is no single inventive concept underlying the plurality of claimed inventions.

6. Five different products are presented in Groups III, IV, VIII, IX and X. Two of the five products (Groups III and IV) share a common property or activity (i.e. screening for cancer) but do not share common core structures. Two of the five products (Groups VIII and IX) share a common property (i.e. providing a prevention/treatment effect) but do not share common core structures. The polynucleotide of Group III, the antibody of Group IV, the polynucleotide vaccine of Group VIII, the polypeptide vaccine of Group IX, and the polypeptide product of Group X are all structurally and chemically different from each other. The polynucleotide is made by nucleic acid synthesis, while the polypeptide

is made by translation of mRNA, and the antibody is raised by immunization. The polynucleotide and the polypeptide are not required to have a preventative effect as do the polypeptide and polynucleotide vaccines. Furthermore, the polynucleotide can be used for purifying nucleic acids, the polypeptide can be used for methods of purifying the antibody, and the antibody can be used to immunopurify the polypeptide, for example. The examination of all groups would require different searches in the patent literature and the scientific literature and would require the consideration of different patentability issues.

7. Inventions of Groups I and III, and Groups II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of detecting or monitoring cancer can be practiced with a materially different product such as by MRI, or CATscan, for example. The examination of all groups would require different searches in the patent literature and the scientific literature and would require the consideration of different patentability issues.

8. Inventions of Groups V and III or VIII, and Groups VI and X or IX, and Groups VII and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of prophylaxis or treatment of cancer can be practiced with a materially different product such as small molecule drug, chemotherapy, radiotherapy, etc. The examination of all groups would require different searches in the patent literature and the scientific literature and would require the consideration of different patentability issues.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election of Species Requirement

11. This application contains claims directed to patentably distinct inventions, NOT species: each of the specifically claimed nucleic acids (and protein/peptides encoded by the respective nucleic acid) consisting of the specifically recited sequences (SEQ ID NO: 1, 2 and 3) lack unity of invention because the nucleic acid sequences have no substantial structural similarities although they have a common utility, i.e. screening for cancer. In re Harnisch, 631 F.2d 716, 206 USPQ 300(CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

Furthermore, there are approximately eight different databases that accompany the results of a search of one discrete amino acid or nucleotide sequence and each result set from a particular database must be carefully considered. Hence, the search of two different nucleic acid sequences, and different amino acid sequence in the databases would require extensive searching and review.

Applicant is advised that a reply to this requirement must include an identification of the invention that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a

claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

A. If any one of Groups I, III, V, or VIII is elected, then species (nucleic acid) below must be elected as applicable. This application contains claims directed to the following patentably distinct species:

1. nucleic acid sequence of SEQ ID NO:1 (TACCI)

2. nucleic acid sequence of SEQ ID NO:2 and 3 (SEQ ID NO:3 is a splice variant of SEQ ID NO:2 for the AD034 gene).

OR

B. If any one of Groups II, IV, VI, VII, IX or X is elected, then species (protein encoded by a nucleic acid) below must be elected as applicable. This application contains claims directed to the following patentably distinct species:

1. protein encoded by nucleic acid sequence of SEQ ID NO:1 (TACCI gene)

2. protein encoded by nucleic acid sequence of SEQ ID NO:2 and 3 (SEQ ID NO:3 is a splice variant of SEQ ID NO:2 for the AD034 gene).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed invention for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LAB

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